REMARKS

Claims 1, 3 to 90, 99, and 100 are pending in this application. Claims 91 to 98 and 102 are herein cancelled without prejudice or disclaimer. Applicants reserve the right to file one or more divisional applications directed to non-elected or cancelled subject matter. Claims 1 and 3 to 90 are allowed. Claims 99 and 100 are rejected under 35 U.S.C. § 112, second paragraph. Claim 100 is rejected under 35 U.S.C. § 112, first paragraph. Reconsideration of Claims 99 and 100 in view of the remarks found hereinbelow is respectfully requested.

Amendments to Claims

Applicants are herein amending claims 99 and 100 to replace the term "at least one" with the Examiner's suggested term "one or more". Applicants are herein further amending claim 100 to specify the organism whose exposure in a patient is targeted using the method of claim 100. Applicants explicitly reserve the right to file one or more continuing applications directed to the cancelled subject matter.

Applicants submit that the amendments to the claims do not introduce new matter and are fully supported by the specification and claims, as originally filed. Applicants request the entry of the amendment under 37 C.F.R. § 1.116(b) because the amendments to the claims either cancel claims, comply with requirements of form expressly set forth in a previous Office Action, or present the rejected claims in better form for consideration on appeal.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 99 and 100 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully submit that the term "at least one" compound according to claim 1 is not indefinite. However, in order to facilitate prosecution, Applicants have amended claims 99 and 100 to replace "at least one" with the Examiner's suggested term "one or more". Applicants respectfully submit that claim 99 as amended is in condition for allowance and request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 100 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for preventing the infections embraced in claim 100. The Office Action further asserts that the specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with claim 100. Applicants traverse the rejection. Without addressing the merits of the rejection, however, Applicants are herein amending claim 100 for the sole purpose of facilitating prosecution of this case. In light of the amendment to claim 100, Applicants respectfully submit that the rejection is moot. Applicants also reserve the right to file one or more continuation applications directed to non-elected or cancelled subject matter.

The Office Action asserts that Applicants provide no evidence for prevention of malaria. However, the test under 35 U.S.C. § 112, first paragraph, is whether one ordinarily skilled in the relevant art, once equipped with the teachings of the present invention, could use the method claimed. One of ordinary skill in malarial prevention and/or treatment understands prevention (prophylaxis) in a malarial context to mean chemoprophylaxis.[1] Chemoprophylaxis may refer to absolute prevention of infection (i.e. causal prophylaxis) or to suppression of parasitaemia and its symptoms (i.e. suppressive or clinical prophylaxis). Drugs, which act on the erythrocytic stages of the parasite (i.e. once the parasite has invaded the red blood cells) are known as blood schizonticides and are suppressive prophylactics. These medicines suppress the disease by destroying the asexual parasites but have no effect on the intrahepatic forms. Examples of blood schizonticides include chloroquine, mefloquine, quinine, halofantrine, pyrimethamine, sulphonamides and sulfones. If prophylaxis is continued until there are no more parasites entering the blood, then a suppressive cure is achieved.

One ordinarily skilled in the art also knew of other commercially available anti-malarial drugs at the time the subject application was filed, such as Daraprim®, Malarone™, Plaquenil®, Lariam®, and Aralen®. These drugs, which are widely used to treat acute

[1] "*Malaria Prophylaxis Guidelines for the Prevention of Malaria in South Africa*" ,a report issued by the South Africa Department of Health on March 1, 2003 in close collaboration with malarial experts. Applicants further bring to the attention of the Examiner that the South African report indicated the guidelines were in keeping with the existing World Health Organization's guidelines for the prevention of malaria. A copy of the South African report has been provided for your convenience. The report may also be found on the Internet at http://www.doh.gov.za/docs/factsheets/guidelines/malaria/prevention.pdf

malarial (Plasmodia) infections, are also indicated for use as chemoprophylactic agents (either absolute or suppressive prophylaxis). Support for this prophylactic use of anti-malarials may be found in the "*Physician's Desk Reference*", 56th Ed, 2002 (best available copy of appropriate pages submitted for your convenience) under the Indications Section for anti-malarial drugs Daraprim®, Malarone™, Plaquenil®, Lariam®, and Aralen® . This reference not only provides the indication of prophylactic use for these antimalarials, but discloses dosage levels, contraindications, pharmacology, adverse reactions, and the like. Therefore, one of ordinary skill in the art would understand that, in general, drugs which are used to treat acute malarial infections could also be used in prophylactic treatment.

In a standard Mouse Malarial Model (Thomson Model) used to ascertain anti-malarial activity, the compounds of the present invention have been shown to have biological activity against *Plasmodia*.[2] The Office Action acknowledges this biological activity. In light of this biological activity and the chemoprophylactic use of other commercial anti-malarial drugs, Applicants respectfully submit that claim 100 is allowable based on the knowledge of one of ordinary skill in the art at the time the invention was filed.

As a further note, chemoprophylaxis is still recommended today by the United States Government to protect travelers going to countries with malarial risk. Applicants respectfully suggest that the Examiner explore the readily accessible Center for Disease Control website (http://www.cdc.gov/malaria/travel/index.htm#protectyourself). A map can be found that indicates the areas where both malaria is transmitted and travelers are at risk of contracting malaria. The same web page, under the heading, **Preventive measures taken by travelers**, states that "[I]individual measures, such as taking an effective antimalarial drug and preventing mosquito bites, are the most important factors in minimizing risk. While other risk factors may be difficult to change or avoid, travelers can greatly reduce their risk of malaria by following recommended travel **precautions** (emphasis added).

[2] The Thompson model, also known as the six-day model, is described in "*Handbook of Experimental Pharmacology*", vol. 68/I, 1984, Springer Verlag, W Peters and W. H. G. Richards, editors beginning at page 231. The 1969 full reference to the Thompson (or six-day) model is cited in "*Handbook of Experimental Pharmacology*" at page 263. A copy of the Appropriate pages from the in "*Handbook of Experimental Pharmacology*" are enclosed for your convenience.

In view of the hereinabove remarks, Applicants respectfully submit that claim 100 as amended is in condition for allowance and request that the rejections under 35 U.S.C. § 112, first and second paragraphs be withdrawn.

Date: October 25, 2006

/Walter C. Frank/
Walter C. Frank
Registration No. 52,911

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439